

REMARKS

Claims 1-19 are pending in this application. Claims 1-19 presently stand rejected under 35 U.S.C. §112; claims 1-6 and 11-17 presently stand rejected under 35 U.S.C. §102; and claims 7-10, 18, and 19 presently stand rejected under 35 U.S.C. §103. Based on the foregoing amendments, and the following remarks, Applicant respectfully requests reconsideration and allowance of claims based on this Amendment.

I. Claim Rejections Under 35 U.S.C. §112

Claims 1-19 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner states, on page 2 of the Office Action, that the limitation "consisting essentially of," in cited independent claims 1 and 11, lacks support in examples 1 and 2. The Examiner notes that Examples 1 and 2 do not positively recite stimulation of other organs. The Examiner then goes on to argue that because they do not exclude stimulation of other organs, they cannot provide support for "consisting essentially of." Applicant respectfully disagrees that there is a lack of support.

Examples 1 and 2, which were carried out using dogs and rats, respectively, do support the use of "consisting essentially of," as does the remainder of the specification. (See Application, page 3, lines 19-22; page 4, lines 1-9 and lines 29-30; page 6, lines 12-15; Examples 1 and 2). The examples are part of the written description and disclose electrostimulation of only the intestines, not any other organs; thus providing a further example of what is not stimulated. The disclosure teaches that only electrostimulation of the intestines is required to treat obesity (see Application, page 1, lines 10-13; page 2, lines 15-18; page 3, lines 14-22; page 4, lines 1-5 and lines 19-25). Furthermore, an Applicant cannot be expected to include an exhaustive list in examples excluding everything that was not done. The Applicant has positively recited what the invention is; that is all that is required.

Section 2111.03 of the MPEP further explains that the transition phrase "consisting essentially of" limits the scope to specified materials and those that do not materially affect the basic and novel characteristics. It is apparent from the examples and the remainder of the specification that the basic and novel characteristics of the invention is the electrostimulation of the intestines to treat obesity. Including other organs in place of the small intestines would materially alter the characteristics of Applicant's invention. One of ordinary skill in the art would clearly understand that Examples 1 and 2 provided only stimulation to the small intestines. Thus, such a person would realize that Applicant was in possession of the invention.

The Examiner states in the Office Action, at page 3, that "the mere absence of a positive recitation is not basis for an exclusion." Applicant notes, however, the lack of literal basis in the specification for a negative limitation may also not be sufficient to establish lack of descriptive support (*see* MPEP §2173.05(j), citing *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993)). *Ex parte Parks* states that an "[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention." 30 USPQ2d at 1236. It further states that "it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." *Id.* As stated previously, Applicant did provide adequate support for the use of the phrase "consisting essentially of." At the least, the disclosure is sufficient to convey to one of ordinary skill in the art of Applicant's possession of the concept of what is claimed.

Therefore, independent claims 1 and 11 comply with the written description of 35 USC §112. Dependent claims 2-10 and 12-19, which depend on independent claims 1 and 11, respectively, also comply with the written description of 35 USC §112. Applicant respectfully requests that this rejection be withdrawn.

II. Examiner's Response to Previous Arguments

Examiner states, in the Office Action at page 3, that there is "no indication that exclusive small intestine stimulation is the 'basic and novel' feature" of the invention and that therefore the previously amended claims 1 and 11 adding the term "consisting essentially of" will be construed as "comprising," in lieu of a 'basic and novel characteristic.' Applicant respectfully disagrees with this statement.

As noted above in section I (which comments are included by reference herein), throughout Applicant's specification there are numerous statements that indicate exclusive small intestine stimulation as the basic and novel features of Applicant's invention; statements such that the electrostimulation is to be provided to the small intestines alone (see Application, page 3, lines 19-22; page 4, lines 1-9; examples 1 and 2); that the leads are attached to, or adjacent to, the small intestines in order to be able to provide the electrostimulation to the small intestines (see Application, page 1, lines 10-13; page 2, lines 15-18; page 3, lines 14-22; page 4, lines 1-9); and that the invention involves providing pulses directed to the small intestines (see Application, page 4, lines 29-30; page 6, lines 12-15). Furthermore, Applicant goes into even further detail as to what part of the small intestine, the duodenum and/or the jejunum, the electrostimulation is *preferably* applied to (see Application, page 1, lines 13-14; page 2, lines 18 and 20-21; page 4, lines 5-9 and 30-31; page 5, lines 2-5; page 6, lines 18-19; examples 1 and 2). The invention is the electrostimulation of the small intestines. Moreover, the claims limit the stimulation to the small intestines. None of the references cited by the Examiner teach the stimulation of only the small intestines as being effective for treating obesity.

Nowhere does Chen teach or suggest such an effect could be achieved by stimulation of the small intestines alone. Therefore, Chen cannot anticipate the present claims. Even Examiner has recognized, on page 3 of the Office Action, that providing stimulation only to the small intestines is "unanticipated by Chen et al.," as explained above, Applicant's disclosure provides stimulation only to the small intestines. There is

nothing ambiguous about what is meant by the disclosure; the disclosure provides for applying electrostimulation to the small intestines alone to treat obesity.

Therefore, Applicant respectfully submits that claims 1 and 11 are unanticipated by Chen, and furthermore, Applicant respectfully submits that the specification and claims do present basic and novel characteristics and that the term "consisting essentially of" does have support throughout the specification to limit the use to the small intestines only.

Additionally, on page 4 of the Office Action, the Examiner states that Chen, at Col. 8, lines 48-50, makes a "clear disclosure of small intestinal stimulation for food transit through the gastrointestinal tract." That is simply not true. At the cited portion, Chen merely states that "if there is rapid small bowel transit or 'dumping' then disrupting this movement with retrograde pacing could be good therapy." (Col. 8, lines 48-50). As will be discussed below in regards to the §102 argument, Chen teaches stimulation of *only* the stomach to treat obesity. Chen discusses that for an obese person it could be advantageous to prolong the time food is kept in the obese patient's stomach through stimulation of the stomach. Chen then adds (at Col. 8, lines 48-50) that if the patient also has a problem with rapid small bowel transit or dumping, that retrograde pacing could be a good therapy for *the dumping*, not for treatment of an obese person, as Examiner has implied. Chen further provides examples of better controlling bowel evacuation by using the pacing program "to work against the natural pacing rhythm of the colon such that the natural pacing rhythm is canceled by some degree" to provide treatment of **diarrhea, dumping syndrome, or irritable bowel syndrome**. (See Col. 9, lines 50-59).

Furthermore, the Examiner goes on to state that since the gastrointestinal tract is a closed system the "slowing motility in the small intestine will *inherently* slow stomach emptying and slow food transit through the digestive system." However, there is nothing in the teachings of Chen to support that stomach motility is affected at all. Moreover, Chen only teaches that the rate of travel through the small intestines is

slowed (and that such treatment is effective for treatment of diarrhea, dumping syndrome, or irritable bowel syndrome), not that any other part of the GI tract is affected or slowed as well, nor that obesity is effectively treated. Per MPEP § 2112, "the examiner must provide a basis in fact and/or technical reasoning to ... support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied prior art." (Emphasis added). There is nothing from the teachings of Chen to show that these characteristics *flow* from it to support Examiner's statement.

Therefore, Applicant respectfully submits that claims 1 and 11 are unanticipated by Chen and that Chen does not disclose or suggest treating obesity or controlling stomach motility by stimulating the small intestines alone.

III. Claim Rejections Under 35 U.S.C. §102(b)

Claims 1-6 and 11-17 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,690,691, issued to Chen et al. (hereinafter "Chen"). Applicant respectfully traverses the rejections under 35 U.S.C. §102 because the cited reference does not disclose each and every limitation of the rejected claims as written or amended, nor are the cited claims obvious in view of Chen.

In particular, the cited reference does not disclose or suggest providing electrical stimulation of the small intestines to alter "the patient's natural gastric motility to prevent or slow down stomach emptying, thereby slowing food transit through the patient's digestive system," as called for in independent claims 1 and 11.

Rather, Chen provides, as illustrated in Figure 5, phased, multi-point electrical stimulation of organs in the gastro-intestinal tract. Chen further provides treating peristaltic flow that is too fast by applying a retrograde, phased pulsing system (i.e., pulses start at a bottom or end of an organ and move up) to overcome the natural pacing of that organ. (See Col. 6, lines 61-63). One example of this is in treating obesity, where Chen teaches applying electrical stimulation directly to the stomach via

electrodes positioned *in or on* the stomach. The electrodes that are *in or on* the stomach are able to override the "natural peristaltic flow through the stomach," which slows down the pacing rate for that organ to treat obesity. (See Col. 7, lines 1-2).

Furthermore, Chen distinguishes the effects achieved from providing electrical stimulation to the stomach from that of the small intestines (i.e., bowels); Chen teaches that providing pacing to the bowel (i.e., small intestines) treats "small bowel syndrome." (See Col. 7, lines 2-4). Chen does not teach or disclose that by applying pacing to the small intestines that obesity would also be treated; Chen differentiates pacing of the bowel as a different treatment than treating obesity. Although Chen discloses applying electrical stimulation to the small intestines (i.e., duodenum), it is not to treat obesity or to slow down stomach movements, but rather for treatment of different (i.e., bowel-related) disorders.

Chen teaches that to treat a disorder (i.e., like obesity) pulsing of the affected organ is necessary to overcome the natural peristaltic flow in that organ. (See Col. 7, lines 34-37). Chen does not disclose or suggest that an organ's peristaltic flow can be altered or affected by pulsing of a different organ. Based on Chen, treatment of obesity by delaying emptying of the stomach would require electrostimulation to the stomach. Electrostimulation of the bowel would only be suitable for a condition associated with the bowel (i.e., small bowel syndrome (Col. 7, lines 2-4); constipation (Col. 6, lines 57-58; Col. 9, lines 48-50); diarrhea (Col. 9, line 52); dumping syndrome (Col. 9, lines 52-53); irritable bowel syndrome (Col. 9, line 53)). Nowhere is it taught or suggested in Chen that electrostimulation of the bowel will have any effect on the stomach. Indeed, Chen teaches away from such an effect since they effectively teach that electrostimulation of the bowel can only effect or treat conditions associated with the bowel.

Therefore, independent claims 1 and 11 are not anticipated by Chen. Dependent claims 2-6 and 12-17, which depend on independent claims 1 and 11, respectively,

cannot be anticipated by Chen for the reasons discussed above with respect to the independent claims. Applicant respectfully requests that this rejection be withdrawn.

IV. Claim Rejections Under 35 U.S.C. §103(a)

Claims 7-10, 18, and 19 have been rejected under 35 U.S.C. §103(a) as being obvious over Chen in view of U.S. Patent 6,449,511 issued to Mintchev et al. (hereinafter "Mintchev"). Applicant respectfully submits that the claims are not rendered "obvious to one having ordinary skill in the art" in view of Chen alone, or combined with Mintchev.

As noted above (which comments are included by reference herein), Chen does not teach or suggest that electrostimulation of the small intestines **alone** (i.e., without concurrent electrostimulation of the stomach) would have any effect, much less the effect required by the claims (i.e., "to prevent or slow down stomach emptying, thereby slowing food transit through the patient's digestive system"), on the stomach. Mintchev does not correct this or other deficiencies noted above with regard to Chen. More specifically, Mintchev does not teach or suggest that electrostimulation of the small intestines alone (i.e., without concurrent electrostimulation of the stomach) would have any effect, much less the effect required by the independent claims (i.e., "to prevent or slow down stomach emptying, thereby slowing food transit through the patient's digestive system"), on the stomach.

Claims 7-10, 18 and 19 are not rendered obvious over Chen alone or in combination with Mintchev. Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicant respectfully submits that all rejections have been overcome and that all pending claims are in condition for allowance.

If the Examiner believes that a telephonic or personal interview would be helpful to terminate any issues which may remain in the prosecution of the Application, the Examiner is requested to telephone Applicant's attorney at the telephone number set forth herein below.

Respectfully submitted,
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